K021197

APR 26 2002

510(k) Summary

Submitter

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Date Prepared
April 5, 2002

Name of Device

Common Name:	Insulin Syringe
Proprietary Name:	**sureone** Insulin Syringe
Classification Name:	Piston Syringe, Hypodermic Single Lumen Needle
Regulation:	880.5860 and 880.5570
Class:	Class II
Product Code:	FMF and FMI

Predicate Devices

The **sureone** Insulin Syringe is substantially equivalent in intended use, function and composition to the currently marketed **sureone** Disposable Insulin Syringes, K002921, and to NovoFine® 31 GA needles, K002403.

Device Description

The **sureone** disposable insulin syringe is used for subcutaneous injection of U-100 insulin. This device is a sterile, single-use, disposable piston syringe with permanently affixed hypodermic single lumen needle. The **sureone** disposable insulin syringe consists of a syringe barrel, a plunger rod, and a hypodermic single lumen needle permanently bonded to the tip of the syringe with epoxy. The **sureone** disposable insulin syringes are available in 1.0cc (100 units), 0.5cc (50 units), and 0.3cc (30 units) syringe capacities with the following sizes of hypodermic single lumen needle: 28 GA x ½", 29 GA x ½", and 30 GA x 3/10". In addition, the 1.0cc and 0.5cc syringe capacities are available with a 31 GA x 5/16" needle.

Intended Use

Insulin syringes are intended only for the injection of U-100 insulin.

Technological Characteristics

The only design change being incorporated into current **sureone** Insulin Syringes compared to currently marketed **sureone** Insulin Syringes is the addition of a new needle size – 31 GA x 5/16" length. This needle has a smaller diameter than the currently marketed **sureone** Insulin Syringes. All other aspects are identical to the currently marketed **sureone** Insulin Syringes. **sureone** Insulin Syringes meet the following standards:

ISO 8537, Sterile, Singe-Use Syringes, with or without Needle, for Insulin
ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2002

Hosuk Company Limited
C/O Ms. Carole Stamp
Regulatory & Clinical Research Institute, Incorporated
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416

Re: K021197
Trade/Device Name: Sureone Insulin Syringe
Regulation Number: 880.5860 and 880.5570
Regulation Name: Piston Syringe, Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMF and FMI
Dated: April 5, 2002
Received: April 16, 2002

Dear Ms. Stamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K021197

Device Name: **sureone** Insulin Syringe

Indications for Use: Insulin syringes are intended only for the injection of U-100 insulin.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)

Nick Hilliard for Pat Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021197